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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,733	11/02/2001	Sunanda R. Kulkarni	MCP-291	3078

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EXAMINER

NAFF, DAVID M

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 05/28/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	10/00733	Applicant(s)	tutarni et al
Examiner	10/00733 D. A. S.	Group Art Unit	1651

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- Responsive to communication(s) filed on 3/4/03.
- This action is FINAL.
- Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

- Claim(s) 7-49 is/are pending in the application.
- Of the above claim(s) 7-49 is/are withdrawn from consideration.
- Claim(s) _____ is/are allowed.
- Claim(s) 7-36 is/are rejected.
- Claim(s) _____ is/are objected to.
- Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The proposed drawing correction, filed on _____ is approved disapproved.
- The drawing(s) filed on _____ is/are objected to by the Examiner.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- All Some* None of the CERTIFIED copies of the priority documents have been received.
- received in Application No. (Series Code/Serial Number) _____.
- received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- Information Disclosure Statement(s), PTO-1449, Paper No(s). 3+4 Interview Summary, PTO-413
- Notice of Reference(s) Cited, PTO-892 Notice of Informal Patent Application, PTO-152
- Notice of Draftsperson's Patent Drawing Review, PTO-948 Other _____

Office Action Summary

In a response of 3/4/03 to a restriction requirement of 1/27/03, applicants elected Group I claims 7-36 without traverse.

Claims 37-49 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no 5 allowable generic or linking claim. Election was made without traverse in Paper No. 6 of 3/4/03.

The U.S. Patent applications listed on page 1 of form PTO-1449 of 3/12/02 have been considered but have been lined through since all have patent numbers except for 09/526,627 which is listed as the parent of 10 this divisional application. The patent numbers of 08/543,975 and 08/421,825 are listed on form PTO-892, and both of these are a division of 08/128,625 which is abandoned.

Claims examined on the merits are 7-36.

Claim Objections

15 Claims 10 and 25 are objected to because of the following informalities: in the claims "manitol" is a misspelling. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 20 112:

25 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7-36 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art

that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification fails to support a tablet containing only lactase and microcrystalline cellulose as in claim 7. According to the 5 specification (page 3, lines 30-35), when only these two components are present, a preblend rather than a tablet exists. Additionally, the preblend is not disclosed as containing the amount of lactase and microcrystalline cellulose as in claim 7. These amounts are described for the tablet (page 4, line 18, and page 5, lines 4-5). The preblend 10 composition is described at page 3, lines 31-36.

The specification fails to support any composition containing amounts of lactase and microcrystalline cellulose as required by claim 22. As noted above, the amounts of claim 22 are described in the specification as being in a tablet, and a tablet is not described 15 containing only lactase and microcrystalline cellulose.

The specification fails to support any mixture of the members of the Markush group of claims 8 and 23. When the members of the group are recited in the specification (page 4, lines 6-13), forming a mixture of any of the members is not disclosed.

20 The specification fails to recite or contain adequate support for a combination of components as required by claims 9-12, 14, 16, 18-21, 24-27, 29-31 and 33-36. The specification fails to recite or support components in combinations as claimed.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

5 (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 15 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

20

Claims 7, 8, 13, 15, 17, 22, 28 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eisenhardt et al (6,410,018) in view of Schwartz et al (4,034,035) and Bowman (3,954,979), and if necessary in further view of Cayle (3,718,739).

25

The claims are drawn to a tablet or composition containing about 3000 to 9000 FCC lactase and about 25-70 weight percent microcrystalline cellulose. Also present may be materials selected from a group of including fillers, lubricants and gums.

Eisenhardt et al disclose a lactase-containing composition that can be in the form of a tablet (col 4, line 34) which can contain fillers or

carriers, diluents, binders, lubricants (col 4, lines 40-47) and microcrystalline cellulose (col 6, lines 10-15).

Schwartz et al and Bowman disclose preparing tablets from a composition containing an enzyme and a mixture of microcrystalline cellulose and corn starch.

Cayle discloses making a tablet containing lactase. A composition from which the tablet is made contains lactase mixed with conventional solid fillers or carriers such as cornstarch, talc, calcium phosphate and calcium sulfate.

It would have been obvious to form the composition of Eisenhardt et al containing lactase and microcrystalline cellulose as a tablet as suggested by Schwartz et al and Bowman et al preparing tablets containing an enzyme and microcrystalline cellulose. Selecting the claimed amounts of lactase and microcrystalline cellulose would have been obvious in view of the disclosures of Eisenhardt et al, Schwartz et al and Bowman. Cayle further discloses preparing a tablet containing lactase and fillers or carriers, and if needed would have further suggested a tablet containing lactase.

Claim Rejections - 35 USC § 103

Claims 9-12, 14, 16, 18-21, 23-27, 29-31 and 33-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over the references as applied to claims 7, 8, 13, 15, 17, 22, 28 and 32 above, and further in view of Shen et al (5,637,561).

The claims require dextrose and sodium citrate and a lubricant which can be magnesium stearate, or mannitol, dextrose, sodium citrate and a gum which can be carboxymethyl cellulose.

Shen et al disclose the commercial lactase which is Lactase F from 5 Amano Co. The present specification discloses (page 3, lines 14-17) that this lactase preparation contains 50% sodium citrate and dextrose.

It would have been obvious to use as the lactase of Eisenhardt et al the known commercially available lactase disclosed by Shen et al that contains sodium citrate and dextrose. Eisenhardt et al discloses 10 carboxymethyl cellulose (col 4, line 44), and mannitol and magnesium stearate (col 4, lines 42-43).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the 15 statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 20) 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based 25 on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record 30 may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 7, 8, 13, 15, 17, 22, 28 and 32 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,365,208 B1 or claims

1-8 of U.S. Patent No. 6,057,139 in view of Schwartz et al and Bowman, and if necessary in further view of Cayle.

The claims of the patents require a formulation containing lactase and microcrystalline cellulose.

5 In view of Schwartz et al and Bowman, and if necessary in further view of Cayle, it would have been obvious to provide this formulation in tablet form for reasons set forth above when applying Schwartz et al, Bowman and Cayle.

Claims 9-12, 14, 16, 18-21, 23-27, 29-31 and 33-36 are rejected
10 under the judicially created doctrine of obviousness-type double over the claims of the patents in view of Schwartz et al and Bowman, and if needed Cayle as set forth above, and in further view of Shen et al for reason set forth above when applying Shen et al.

The U.S. Patent application (09/715,463) listed on form PTO-1449 of
15 3/19/02 has been considered but has been lined through since the application has been abandoned.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David M. Naff whose telephone number is (703) 308-0520. The examiner can normally be reached on
20 Monday-Thursday and every other Friday from about 8:30 AM to about 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, a message can be left on voice mail.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached at telephone number (703) 308-4743.

The fax phone number is (703) 872-9306 before final rejection or
5 (703) 872-9307 after final rejection.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

10

DMN
5/23/03



DAVID M. NAFF
PRIMARY EXAMINER
ART UNIT 1651